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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,206	08/28/2001	Kenton N. Fedde	3376/I US	5686
26648	7590	11/07/2005	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/941,206	Applicant(s) FEDDE ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 13, 14 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 13, 14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and the response filed August 18, 2005 have been received and entered into the application.

Action Summary

The rejection of record under 35. U.S.C. 102 (b) is being maintained for the reasons stated in the previous office action.

The provisional Double Patenting rejection of claims 8, 17 and 38-41 as being unpatentable over claims 1-18 of copending Application No. 10/440,691 is hereby expressly withdrawn in view of Applicant's amendment of cancellation of the claim 8.

The rejection of claims 8, 17 and 38-41 under 35 U.S.C. 102(e) as being anticipated by Thosar et al. (U.S. Patent No. 6,592,902 B2) is hereby expressly withdrawn in view of Applicant's amendment of cancellation of the claims.

The rejection of claims 8,9, 12-17 and 38-41 under 35 U.S.C. 102(e) as being anticipated by Alexander et al. (US 2004/0077611A1) is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 9 and 12-17 under 35 U.S.C. 103(a) as being unpatentable over Tosar et al. (U.S. Patent No. 6,529,902 B2) as applied to

Art Unit: 1617

claims 8, 17 and 38-41 above, and further in view of Applicants' admission is hereby expressly withdrawn.

Upon further consideration, the additional new ground(s) of rejection presented in this Office action.

It is reminded that claims 9, 13, 14 and 17 have been examined only to the extent of the election of Group ii(e). That is the compounds have been searched as to their use of improving "the quality of life is improved in a patient suffering from **heart disease**".

Double Patenting

Claims 9, 13, 14 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/440,691. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The instant claims drawn to method of improving quality of life in an individual suffering from heart disease by administration of eplerenone is fully taught and encompassed by the claims of the copending Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marketletter (April 3, 2000) in view of Lim et al. (1999) and Biomedical Market Newsletter (1999).

The Marketletter teaches eplerenone is the selective aldosterone receptor antagonist providing additional cardiac and vascular protective benefit in post-MI heart failure patients treated. (second paragraph).

The Market letter does not teach the effective amounts and the quality of life assessment of SF-12 health survey and EuroQol Health Rating Scale.

Lim et al. teach SF-12 Health survey is useful in **heart** and stroke patients. (abstract).

Biomedical Market Newsletter teaches SF-36, and European Quality of Life measure (EuroQol) are various patient-based measures of quality of life. (3rd paragraph).

It would have been obvious to one of ordinary skill in the art to employ the eplerenone to improve the quality of life of the patients suffering from post-MI heart failure patients and measure the improvement by SF-12 health survey or EuroQol because eplerenone provide additional cardiac and vascular protective

Art Unit: 1617

benefit in post-MI heart failure patients being treated as taught by Market letter and because SF-12 health survey EuroQol is well known assessment tool to measure quality of life and SF-12 particularly is a useful tool in heart and stroke patients. One would have been motivated to make such a modification in order to effectively treat patients with myocardial infarction resulting in a diagnosis of heart failure by administration of eplerenone by employing well-known survey useful for measuring health status of heart and stroke patients. The amounts of active agents to be used are deemed obvious since it is within the knowledge of the skilled pharmacologist.

Response to Arguments

Applicant's arguments filed August 18, 2005 have been fully considered but they are not persuasive. Applicant's argument regarding claims rejected under judicially created doctrine of Double patenting is not persuasive because Applicant's has filed a terminal disclaimer with the Application (09/518854) that is abandoned not with the application (10/440691) that is at issue. Applicants argue that

None of the claims are allowed.

Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 23, 2005